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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,246	03/10/2004	Brian P. Jacob	02420/1200875-US1	3551
7278	7590	11/24/2010	EXAMINER	
DARBY & DARBY P.C.			SEVERSON, RYAN J	
P.O. BOX 770			ART UNIT	
Church Street Station			PAPER NUMBER	
New York, NY 10008-0770			3731	
			MAIL DATE	DELIVERY MODE
			11/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,246	Applicant(s) JACOB, BRIAN P.	
	Examiner RYAN J. SEVERSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-16 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/27/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-3, 12-16 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger (5,360,414).** Yarger discloses a device capable of use as an endoluminal protection and access device for positioning within a lumen of a gastrointestinal tract comprising an access member (40, see figure 6) including an outer wall (the entire wall is a single layer of material, and therefore the entire wall is considered the "outer wall" as claimed) defining an internal lumen (30, see figure 7). The distal end of the access member is sufficiently blunt such that perforation of the gastrointestinal lumen would be prevented during positioning of the device. The outer

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wall defines windows (28) adjacent the distal end in communication with the internal lumen. The outer wall has a continuous circumference (at 46, see figure 6) forming an enclosed cylindrical section from the window to the proximal end. The material of the access member is disclosed (at column 8, line 17) as being semi-rigid, and therefore is considered to be sufficient to stabilize the gastrointestinal lumen yet flexible enough to permit navigation through a tortuous path. The outer wall defines a slot (26) in communication with the window (see figure 7) and extending to the distal end of the access member. The slot runs parallel to the longitudinal axis of the access member. A housing (24) defining a port at the proximal end of the access member is capable of use for permitting ingress and egress of insufflation gases.

4. However, Yarger fails to disclose the window extending from 90-180 degrees around the circumference of the access member. However, Examiner points out Yarger makes clear the size of the holes can be adjusted (see column 5, line 53). It has been held that where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Further, it has been held that absent persuasive evidence that the particular configuration of the claimed window is significant, a person of ordinary skill in the art would have found it obvious to shape the prior art window in the claimed shape/configuration. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

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5. Therefore, in view of the clear suggestion from Yarger that the size of the windows can be controlled, and the case law cited above, Examiner contends one having ordinary skill in the art at the time the invention was made would have found it obvious to have made the windows of Yarger in a size and shape such that they define a radial arc of 90-180 degrees around the circumference of the access member.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 20 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN J. SEVERSON whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J Severson/
Examiner, Art Unit 3731
11/22/10